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Notice to Readers: FDA Licensure of Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant), and Poliovirus Vaccine Combined, (PEDIARIX™) for Use in Infants

Please note: A clarification has been published for this article. To view the clarification, please [click here](#).

On December 13, 2002, the U.S. Food and Drug Administration (FDA) licensed a combined diphtheria and tetanus toxoids and acellular pertussis adsorbed (DTaP), hepatitis B (HepB) (recombinant) and inactivated poliovirus vaccine (IPV), DTaP-HepB-IPV (PEDIARIX™, SmithKline Beecham Biologicals, Rixensart, Belgium) for use in infants ages 2, 4, and 6 months. All components in the combined vaccine are recommended for routine use by the Advisory Committee on Immunization Practices (ACIP), the Committee on Infectious Diseases of the American Academy of Pediatrics, and the American Academy of Family Physicians (1,2). Combination vaccines decrease the number of vaccine injections (3).

Each dose of DTaP-HepB-IPV contains the type and amount of diphtheria and tetanus toxoids and pertussis antigens and hepatitis B virus antigens as the DTaP and pediatric formulation of hepatitis B vaccine from the same manufacturer (INFANRIX® and Engerix-B®, respectively). The poliovirus component of DTaP-HepB-IPV contains the same strains and quantity of inactivated poliovirus Types 1, 2, and 3 as IPV from a different manufacturer (IPOL®, Aventis Pasteur, South Africa) (4).

The immunologic responses following 3 doses of DTaP-HepB-IPV were generally similar to those following 3 doses of separately administered INFANRIX®, ENGERIX-B®, and oral poliovirus vaccine (5). Immunogenicity data from simultaneous administration of DTaP-HepB-IPV, with both *Haemophilus influenzae* type b (Hib) conjugate vaccine and pneumococcal conjugate vaccine (PCV), are unavailable (4).

Except for fever, the rates of most solicited local and systemic adverse events following DTaP-HepB-IPV were comparable to rates observed following separately administered U.S.-licensed vaccines. In comparative studies, administration of DTaP-HepB-IPV and Hib vaccine was associated with higher rates of fever relative to separately administered vaccines (5,6). In an ongoing study, infants who received the first dose of DTaP-HepB-IPV with Hib vaccine and PCV had higher rates of fever

compared with infants who received separately administered vaccines (4).

ACIP Approval of DTaP-HepB-IPV for the Vaccine for Children Program

ACIP has approved the use of PEDIARIX™ for the Vaccine for Children program and recommends that, in addition to FDA-approved uses, 3 doses of PEDIARIX™ can be administered to an infant who is born to a woman who is hepatitis B surface antigen (HBsAg)-positive or whose HBsAg status is unknown. ACIP also approved a minimum interval of 4 weeks between the first and second doses when used in an accelerated vaccination schedule; the third dose should not be given before age 24 weeks.

Indications and Usage

Primary series

1. DTaP-HepB-IPV is approved for the primary series at ages 2, 4, and 6 months. The vaccine should not be administered to any infant aged <6 weeks or any person aged ≥7 years. The recommended interval between doses is 6--8 weeks (preferably 8 weeks) (4).
2. DTaP-HepB-IPV can be used to complete the primary series in infants and children who have received INFANRIX® (DTaP) and are scheduled to receive the other components of the combination. Data are limited on the safety and immunogenicity of interchanging currently used DTaP vaccines from different manufacturers (7). ACIP recommends that, whenever feasible, the same brand of DTaP should be used for the primary series but that vaccination should not be deferred because the type of DTaP previously administered is unavailable or unknown (7).
3. All infants should receive a single antigen HepB vaccine soon after birth and before hospital discharge; the first dose can be given by age 2 months if the infant's mother is HBsAg-negative (1). For optimal prevention of perinatal infection, infants born to women who are HBsAg-positive must receive their first dose of single antigen HepB vaccine and hepatitis B immune globulin (HBIG) within 12 hours of birth and ≥3 doses of HepB vaccine by 6 months of age. Women of unknown HBsAg status who give birth should be tested for HBsAg immediately and their infants administered single antigen HepB vaccine within 12 hours of birth; these infants also should receive HBIG if the woman is found to be HBsAg-positive. Except for doses administered at age <6 weeks of age, DTaP-HepB-IPV can be used in a HepB vaccine series for any infant. However, infants born to HBsAg-positive women should begin DTaP-HepB-IPV beginning by age 6--8 weeks after receiving single antigen vaccine at birth. Use of DTaP-HepB-IPV after single antigen HepB vaccine is administered at birth will result in a 4-dose HepB vaccine series (1); this is considered acceptable by ACIP (3).
4. DTaP-HepB-IPV and HepB vaccine from a different manufacturer are interchangeable for HepB vaccination (3). DTaP-HepB-IPV and IPV from a different manufacturer are interchangeable for poliovirus vaccination (4).
5. DTaP-HepB-IPV combination can be administered with Hib and PCV vaccines at separate injection sites (7).

Boosters

1. The DTaP-HepB-IPV combination is not approved for the fourth dose of IPV or the fourth and fifth dose of DTaP (4).

References

1. CDC. Recommended childhood immunization schedule---United States, 2003. *MMWR* 2003;52:Q1-Q4.
2. Pickering LK, ed. 2000 Red Book: Report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, Illinois: Academy of Pediatrics, 2000.
3. CDC. Combination vaccines for childhood immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). *MMWR* 1999;48(No. RR-5).
4. PEDIARIX™ [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivates Poliovirus Vaccine Combined] Prescribing information. SmithKline Beecham Biologicals, Rixensart, Belgium, December 2002.
5. Yeh SH, Ward JI, Partridge S, et al. Safety immunogenicity of a pentavalent diphtheria, tetanus, pertussis, hepatitis B and polio combination vaccine in infants. *Pediatr Infect Dis J* 2001;20:973--80.
6. Zepp F, Schuind A, Meyer C, Sanger R, Kaufhold A, Willems P. Safety and reactogenicity of a novel DTPa-HBV-IPV combined vaccine given along with commercial Hib vaccines in comparison with separate concomitant administration of DTPa, Hib, and OPV vaccines in infants. *Pediatrics* 2002;109:58.
7. CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). *MMWR* 2002;51(No. RR-2).

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